IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

BOND PHARMACY, INC., d/b/a AIS HEALTHCARE,

Plaintiff

v.

CIVIL ACTION NO. 3:23-cv-3158-CWR-LGI

MERRICK GARLAND, in his official capacity as the Attorney General of the United States, 950 Pennsylvania Avenue, NW, Washington, DC 20530-0001;

U.S. DEPARTMENT OF JUSTICE, 950 Pennsylvania Avenue, NW, Washington, DC 20530-0001;

ANNE MILGRAM, in her official capacity as the Administrator of the Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; and

DRUG ENFORCEMENT ADMINISTRATION, 8701 Morrissette Drive, Springfield, VA 22152;

Defendants.

PLAINTIFF'S VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Bond Pharmacy, Inc., d/b/a AIS Healthcare ("AIS"), brings this Verified Complaint for declaratory and injunctive relief against the Honorable Merrick Garland, in his official capacity as the Attorney General of the United States, the U.S. Department of Justice, the Honorable Anne Milgram, in her official capacity as Administrator of the Drug Enforcement Administration ("DEA Administrator"), and the Drug Enforcement Administration ("DEA," collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This case is a textbook example of government overreach and abuse that, absent injunctive and declaratory relief, will result in devasting and irreparable harm to a healthcare provider and the tens of thousands of patients who depend on its specialized and vital care.

2. AIS is a specialty compounding pharmacy and home infusion therapy ("HIT") provider that develops bespoke medications for chronically ill patients, many of whom suffer from cancer and spastic conditions such as multiple sclerosis. These vulnerable patients rely on access to AIS's medications daily to live their lives pain free and without being opioid-addled, bed-ridden, or mired in in-patient facilities.

3. As part of its care, AIS dispenses – that is, develops and ships – custom medications for these patients that are filled into their surgically implanted intrathecal pumps and administered through the pump to the patient's spinal column on a continuous basis, meaning 24/7/365. With its intrathecal HIT therapy, AIS allows patients to regain control of their lives and avoid the devastating effects of oral opioids, among other benefits. This form of care also significantly reduces healthcare costs to payors.

4. In the main, AIS dispenses the patient's medication to a treating physician's office for refills. Patients and treating physicians overwhelmingly prefer in-office refills because of the sterility of a physician's office and availability of emergency care should any complications arise.

5. Moreover, given these medications are controlled substances packaged in large 20 ml to 50 ml syringes, shipping them to a patient's doorstep is not a viable option because of the risks of diversion and possible harm to third-parties. As common sense dictates, these syringes have no place next to a patient's packages and mail.

6. Years ago, in 2016, AIS obtained approval from the Defendants to dispense its medications to physicians' offices.

7. AIS followed that advice, and thus accordingly has dispensed its medications to physicians for years without issue.

8. But with a terse letter dated December 14, 2023, in only a few sentences and devoid of any explanation or basis, including an effort to explain away its prior advice, the DEA immediately directed AIS to cease and desist from all distribution of its vital medications to physician offices from its pharmacy located in Ridgeland, Mississippi.

9. In doing so, the DEA did not initiate a show cause proceeding – as required by law – or provide AIS with any notice, an opportunity to be heard, or any due process whatsoever. Nor did it even address its earlier, contrary direction to AIS.

10. As a result of their summary edict, Defendants have left AIS with a true Hobson's choice: stop dispensing critical medications to patients that count on them to live, which will undermine these patients' health and well-being and jeopardize AIS's ability to remain a going concern, or continue to care for its patients while facing criminal and civil consequences for doing so.

11. Through their conduct, Defendants have violated federal law. Defendants' attempt to strong-arm AIS out of business and ignore mandatory procedures and requirements constitute flagrant violations of AIS's fundamental constitutional rights and basic precepts the Administrative Procedure Act ("APA").

12. Accordingly, AIS needs immediate injunctive relief to enjoin Defendants from enforcing their unlawful directive and prevent the imminent and irreparable harm that AIS, its patients, and the public will suffer absent such necessary and appropriate relief.

PARTIES

13. AIS is incorporated in Mississippi with its principal place of business in Ridgeland, Mississippi.

14. Defendant Merrick Garland is named in his official capacity as the Attorney General of the United States. Under 21 U.S.C. § 824(d), the Attorney General is given the authority to "suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety."

15. The Attorney General has delegated that authority to the DEA Administrator. *See* 28 C.F.R. § 0.100. The U.S. Department of Justice is an executive department of the United States. *See* 5 U.S.C. § 101; 28 U.S.C. § 501. The head of the Department of Justice is the Attorney General. *See* 28 U.S.C. § 503.

16. Defendant Anne Milgram is named in her official capacity as Administrator of the DEA. The Attorney General's authority to suspend or revoke DEA registrations pursuant to 21 U.S.C. § 824(d) has been delegated to her. *See* 28 C.F.R. § 0.100.

17. Defendant DEA is an agency of the U.S. Department of Justice. It was created by Executive Order 11,727. *See* 38 Fed. Reg. 18,357 (July 10, 1973).

JURISDICTION AND VENUE

18. This Court has jurisdiction over this action under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and the APA.

19. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States and a substantial part of the events giving rise

to AIS's claims occurred in this judicial district. The DEA letter was issued from an office in this District.

20. This Complaint is timely under 28 U.S.C. § 2401(a).

FACTUAL ALLEGATIONS

AIS Provides Specialized HIT Services To Critically Ill And Vulnerable Patients

21. AIS is a licensed compounding pharmacy and healthcare provider, registered with the DEA, that provides specialty home infusion therapy ("HIT") and related services.

22. HIT is the creation, dispensing, and infusing of medication by non-oral means.

23. Under this therapy, patients receive a continuous, daily treatment at home – as opposed to an in-patient, hospital setting – and can resume normal lifestyles and work activities while recovering from illness.

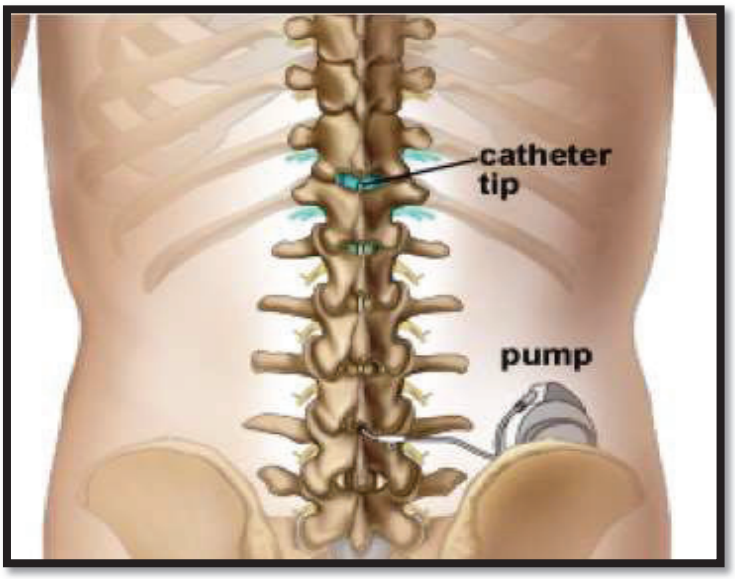
24. If HIT were not available, these patients would either have to take mind-addling oral opioids (and be exposed to their potentially devastating side-effects), or live out their days in an in-patient treatment facility.

25. HIT is typically prescribed for patients who have serious and abiding illnesses such as chronic pain resulting from cancer, spinal cord injuries, multiple sclerosis, or other debilitating conditions. It is also a "last-line" therapy because all other therapies have failed to treat a patient's condition.

26. AIS operates in a specialized area of HIT. It develops and dispenses patient-specific compounded pain medications at the direction of a patient's treating physician that are continuously infused via implanted intrathecal pumps.

27. These pumps, which are prescribed by a patient's treating physician, are surgically implanted under the patient's skin and filled with medication that the pump

administers through a catheter to the spinal column wherever the patient is located, as the following illustration shows:



[1]

28. Intrathecal pumps can administer a patient's medication daily for up to 180 days before needing to be refilled.

29. The medications used for intrathecal pumps have to be specially prepared for each patient to remain stable, sterile, and effective for up to 180 days between refills. Indeed, it takes weeks for AIS to compound the medications because of the complex sterility procedures and testing it must undertake eliminate all impurities.

30. These medications are not readily available from retail commercial pharmacies; they must be developed for each patient in sterile environments and using specialized and highly technical procedures.

31. Thus, AIS's patients cannot readily obtain the same medications from retail pharmacies or even competitors. Indeed, AIS is one of the largest intrathecal HIT providers in

[1] Mayfield Clinic, *Pain Pump*, at 1, https://d3djccaurgtij4.cloudfront.net/pe-pain-pump.pdf (last visited December 15, 2023).

the country and, unlike other providers, cares for patients in all 50 states who count on continued access to its therapy.

32. But AIS does more than develop custom medications. AIS provides all patients with access to a host of ongoing care and services, such as clinical services, coordination of patient care, nursing services, and billing support services.

33. Critically, a patient's intrathecal pump must remain filled with medication at all times. Without the medication, the pump will not properly operate. They are designed to have medication flowing through them at all times.

34. Without consistent access to intrathecal compounded medications, patients will remain in constant pain and misery – all of which intrathecal HIT is specifically designed to treat – and at risk of other serious medical complications

35. Patients with a dry pump may face serious harm – even death.

36. When a pump runs dry, a patient can go into severe withdrawal and suffer other significant and harmful side effects.

37. For example, a patient suffering from multiple sclerosis can lose control of spasticity that would otherwise be treated with AIS's therapy, leading to possible seizures and strokes.

38. Moreover, without access to AIS's medications, these patients will have to revert back to in-patient care, losing access to the physical freedoms associated with having their treatment and therapy follow them wherever they may go.

The Controlled Substances Act

39. The Controlled Substances Act ("CSA") establishes controls and restrictions on the import, export, manufacture, and distribution of controlled substances. 21 U.S.C. § 801 *et seq.*; *id.* § 95l *et seq.*; 21 C.F.R. Part 1300 *et seq.*

40. The DEA is tasked with enforcing the CSA in a balanced manner that prevents the diversion of controlled substances from legitimate channels while ensuring their availability for legitimate medical purposes. *See* 76 Fed. Reg. 39,318 (July 6, 2011).

41. The CSA requires all persons who dispense controlled substances to obtain a registration from the Attorney General. *See* 21 U.S.C. § 822(a).

42. The Attorney General has delegated this registration authority to the DEA. *See* 28 C.F.R. § 0.100.

43. For a specialty pharmacy, such as AIS, this registration authorizes the pharmacy to dispense certain controlled substances.

44. Under the CSA's regulations, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner." 21 C.F.R. § 1306.06.

45. The administration and dispensing of narcotic drugs is further governed by 21 C.F.R. § 1306.07.

46. From July 25, 2005, to October 29, 2020, 21 C.F.R. § 1306.07 did not specifically address whether a pharmacy was permitted to dispense controlled substances to a treating physician, instead of directly to a patient.

47. On October 30, 2020, 21 C.F.R. § 1306.07 was amended to include subsection (f), which is still present in the regulation today.

48. In relevant part, 21 C.F.R. § 1306.07(f) states "a pharmacy may deliver a controlled substance to a practitioner . . . if":

- "(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance," and
- "(2) The controlled substance is to be administered for the purpose of maintenance or detoxification treatment"; and
    - (i) "The practitioner . . . is a qualifying practitioner"; and
    - (ii) "The controlled substance is to be administered by injection or implantation";
- (3) The pharmacy and the practitioner are authorized to conduct such activities specified in this paragraph (f) under the law of the State in which such activities take place."

49. Thus, as the regulation makes clear on its face, the purpose is to ensure patients receive oversight and care while controlled substances and related treatments are administered. *See id.*

50. Under the CSA, the DEA can revoke, restrict, or suspend a registration upon a finding that the registrant has, among other things, "committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4).

51. Alternatively, a registration may be immediately suspended upon a finding that there "is an imminent danger to the public health or safety" evidenced by a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d).

52. But prior to revoking or restricting a DEA registration, the agency must follow mandatory procedures designed to provide a registrant with notice and an opportunity to be heard.

53. The DEA must issue an order to show cause setting forth the basis for the agency's proposed action, providing notice of the opportunity for the registrant to submit a corrective action plan, and providing the registrant with the opportunity to request a hearing. *See id.* § 824(c)(1)-(2).

54. At such a hearing, the agency has the burden of proving by a preponderance of the evidence that registration is inconsistent with the public interest. *See* 21 C.F.R. § 1301.44(d).

55. For immediate suspensions under Section 824(d), the order "shall contain a statement of . . . findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e).

56. The DEA must comply with established procedures and protocols before acting to revoke or restrict a DEA registration or related actions. *See* 21 U.S.C. §§ 824(c)(1)-(2) & (d); 21 C.F.R. § 1301.44(e).

The DEA Confirms That AIS's Dispensing Of Compounded Medications To Treating Physicians Is Permissible Under The CSA

57. On October 9, 2015, counsel for AIS contacted the DEA to clarify whether a pharmacy – such as AIS – may deliver controlled substances to a treating physician, instead of directly to a patient, for refills under certain circumstances under the CSA. Exhibit ("Ex.") A.

58. AIS proactively sought guidance from the DEA because the CSA did not address such a scenario.

59. AIS wanted to ensure it fully complied with all applicable laws and regulations while providing its therapy and services.

60. The DEA responded to AIS's request on July 12, 2016. *See id.*

61. In its response, the DEA confirmed that "[n]either the CSA nor DEA regulations specifically address" delivering controlled substances to a treating physician under certain circumstances. *Id.*

62. Nevertheless, the DEA confirmed that AIS's proposed practice of dispensing its medications to treating physicians fully complied with the CSA.

63. The DEA used the following scenario to evaluate AIS's inquiry:

- "A DEA-registered practitioner, acting in the usual course of his/her professional practice, issues a prescription for a controlled substance for a legitimate medical purpose, and the prescription complies in all other respects with the DEA regulations.
- The practitioner determines, in the exercise of his/her sound medical discretion, that it is appropriate for the practitioner to administer the controlled substance directly to the patient at the practitioner's registered location.
- The prescription is for a single dose of the controlled substance for a particular patient – not a take-home supply for that patient and not for the practitioner's office stock.
- The practitioner indicates on the prescription that the controlled substance should be delivered by the pharmacy to the practitioner, at his/her registered location, for administration to the patient.
- The above activity is carried out in compliance with applicable State law and regulations." *Id.*

64. Applying the scenario under which AIS would deliver its compounded medications to a treating physician, the DEA made clear that it "*would consider it permissible* under the CSA and DEA regulations for [AIS] to deliver the controlled substance to the practitioner, at his/her registered location," provided the following conditions are met:

- "The pharmacy treats its actions as dispensing for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder," *id.*; and

- "The practitioner treats his/her actions as administering for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder," *id.*

65. Following the DEA's confirmation, AIS adhered to the DEA's directive.

66. AIS shipped patient medications to their treating physicians for refills *for years* without issue in compliance with the DEA's conditions and directive.

67. Indeed, despite further routine inspections from the DEA and other boards and agencies, they never once raised any concerns or issues with AIS's dispensing practices to practitioners or compliance with the CSA or found AIS failed to comply with the DEA's direction.

The DEA Improperly, Without Basis, And Contrary To Its Earlier Direction, Demands AIS Cease And Desist Dispensing Of Its Medications

68. On November 2, 2023, the DEA Jackson District Office conducted an on-site inspection of AIS.

69. The inspection itself was standard and routine. During the inspection, the DEA explained that it did not uncover any issues or concerns related to AIS's operations and procedures.

70. Nevertheless, on December 14, 2023, the DEA – out of the blue – served a letter on AIS (dated December 12, 2023). Ex. B.

71. In the letter, the DEA claimed that, during its latest inspection, it "learned" that AIS had been "providing patient specific pain medications" to treating physician offices – even though AIS had been dispensing its medications to physicians for refills for years, as the DEA knew and previously approved. *Id.*; *see also* Ex. A.

72. Notably, the DEA did not state or find that AIS had been doing so inconsistently with its previously-stated conditions and direction.

73. The DEA then quoted 21 C.F.R. § 1306.07(f) without expressly stating whether or not AIS was in compliance with the regulation.

74. After quoting the regulation in the one-page letter, and without any further notice, explanation, or opportunity for AIS respond, the DEA demanded AIS to "cease and desist any further shipments of its compounded medications directly to [treating physicians]" of AIS patients from its Ridgeland-based pharmacy. Ex. B.

75. The Ridgeland, Mississippi pharmacy is AIS's most active pharmacy and dispenses the largest volume of AIS's medications to patients across the United States.

76. AIS cannot remain a going concern and meet its patients' medical needs if the Ridgeland pharmacy is shut down, even temporarily.

77. The DEA did not issue an order to show cause setting forth the basis for demanding AIS to cease and desist its pharmacy shipments or afford AIS the right to request a hearing, as required under the CSA. 21 U.S.C. § 824(c)(1)-(2).

78. Nor did the DEA establish at a hearing, and by a preponderance of the evidence find, that AIS had violated the CSA and regulations – which it must do under the CSA. *See id.*; 21 C.F.R. § 1301.44(d).

79. Within an hour of receiving the DEA's correspondence, AIS contacted the agency by telephone in hopes of amicably resolving the issue.

80. Counsel for AIS further contacted the agency, alerting them to the fact that it intended to seek preliminary relief should the agency refuse to engage or withdraw its directive. *See* Exs. C & D.

81. But the DEA never responded.

Defendants' Unlawful Conduct Threatens Severe And Irreparable Harm To AIS, Its Patients, And The Public

82. Defendants' unilateral and unlawful directive to force AIS to shut down its dispensing operations is already causing severe and irreparable harms and threatening to cause more catastrophic harms if it cannot be resolved soon.

83. Defendants' directive has prevented AIS from providing vital and critical medications and services to current patients in Mississippi and across the United States.

84. And if it remains in place, thousands of chronically ill and vulnerable patients will be unable to receive the benefits of AIS's therapy and care and face serious harm – and possibly death – should their pumps run dry.

85. AIS's patients will likely suffer significant harm, including pain, withdrawal, seizures, and strokes, or even die if their medications are not delivered and their pumps are not refilled. Even just a few days of halting dispensing operations means hundreds of patients will go without their medications; by next week, it will be thousands.

86. AIS serves tens of thousands of patients, who cannot simply switch to another provider on a moment's notice. Nor can their treating physicians.

87. Defendants have further undertaken a final agency action without complying with any of the mandatory procedures, including but not limited to the DEA's own hearing and notice requirements.

88. And in doing so, Defendants have further directly contradicted their own directives and past approvals of AIS's dispensing practices and operations – all of which they knew and approved of *for years*.

89. Defendants have also deprived AIS of its constitutional right to due process by denying it any opportunity to be heard or challenge Defendants' unlawful conduct while at the very same time depriving AIS of its protectable property interests.

90. Moreover, by preventing AIS from dispensing its medications from its primary pharmacy, the company cannot remain a going concern if it cannot dispense and provide its medications and therapy to its existing and future patients.

91. And if AIS cannot provide patients with their medications and services, AIS's relationships with its patients will be jeopardized, and it will suffer concomitant harm to its goodwill, reputation, financial position, and market and competitive position. It will also likely fall in breach of its loan covenants, further exacerbating an untenable financial position.

92. These harms are all irreparable, and AIS lacks any adequate remedy at law.

93. AIS has tried amicably to resolve the parties' dispute to no avail.

94. Left with no other option, AIS reluctantly turns to this Court to force Defendants to comply with federal law. Without judicial relief, AIS will continue to suffer grave and irreparable harms.

CAUSES OF ACTION

COUNT I
(Violation Of 5 U.S.C. § 706(2)(A) – Arbitrary And Capricious Agency Action)

95. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

96. The DEA's December 14, 2023 directive – as approved and directed by Defendants – is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

97. AIS is adversely affected and aggrieved by the directive.

98. Defendants' decision to issue its directive for AIS to cease and desist shipments of its compounded medications "directly to the practitioner" is arbitrary and capricious.

99. Defendants failed to engage in reasoned decision-making; to consider important aspects of the problem they believed they faced; to reasonably (or at all) explain their departure from DEA's established past policy and rule interpretation; to consider more narrowly tailored remedies and the impact that the letter would have on the public health; and to provide an adequate explanation for their decision.

100. As a result, the directive is arbitrary, capricious, and otherwise not in accordance with the law in violation of 5 U.S.C. § 706(2)(A).

101. AIS has suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(A).

102. AIS is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT II
(Violation Of 5 U.S.C. § 706(2)(B) – Agency Action In Violation Of Due Process)

103. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

104. The DEA's December 14, 2023 directive – as approved and directed by Defendants – is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

105. AIS is adversely affected and aggrieved by Defendants' directive.

106. The directive denied AIS prior notice of the allegations against it and a meaningful opportunity to contest those allegations prior to Defendants' directive immediately to cease and desist shipments of its compounded medications "directly to the practitioner."

107. Depriving AIS of prior notice and a hearing was not necessary to further any government interest, deprived AIS's due process rights afforded by law and the U.S. Constitution, and impaired AIS's property interest in its DEA registration.

108. Accordingly, the directive is contrary to AIS's constitutional rights, power, and privilege in violation of 5 U.S.C. § 706(2)(B).

109. AIS has suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(B).

110. AIS is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT III
(Violation Of 5 U.S.C. § 706(2)(C) – Agency Action In Excess Of Statutory Authority)

111. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

112. The DEA's December 14, 2023 directive – as approved and directed by Defendants – is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

113. AIS is adversely affected and aggrieved by the directive.

114. The directive is not authorized pursuant to 21 U.S.C. § 824(a) because Defendants failed to issue a show cause order.

115. The directive is not authorized pursuant to 21 U.S.C. § 824(d) because Defendants did not demonstrate that AIS must stop shipments of its compounded medications "directly to the practitioner" to prevent "imminent danger to the public health or safety."

116. Defendants accordingly did not have the statutory authority to issue their directive.

117. The directive to cease and desist also exceeds Defendants' statutory jurisdiction under 21 U.S.C. §§ 824(a) & (d).

118. As a result, the directive is in excess of statutory authority, jurisdiction, and limitations, in violation of 5 U.S.C. § 706(2)(C).

119. AIS has suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(C).

120. AIS is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT IV
(Violation Of 5 U.S.C. § 706(2)(D) – Agency Action Without Observance Of Procedure Required by Law)

121. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

122. The DEA's December 14, 2023 directive – as approved and directed by Defendants – is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

123. AIS is adversely affected and aggrieved by the directive.

124. A registration granted under 21 U.S.C. § 823 may be suspended upon a finding that the registrant "failed to comply with any standard referred to in 21 U.S.C. § 823(h)(1)[.]" 21 U.S.C. § 824(a).

125. Prior to taking action under 21 U.S.C. § 824(a), a registrant must be served an order to show cause why registration "should not be denied, revoked, or suspended." 21 U.S.C. § 824(c)(1).

126. A registration granted under 21 U.S.C. § 823 may be immediately suspended under Section 824(d) upon a finding that there "is an imminent danger to the public health or safety" evidenced by a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d).

127. An order under 21 U.S.C. § 824(d) suspending a registrant "shall contain a statement of . . . findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e).

128. The directive was not accompanied by an order to show cause or a statement of findings regarding the danger to public health or safety posed by shipments of AIS's compounded medications "directly to the practitioner."

129. Thus, the directive was issued "without observance of procedure required by law" in violation of 5 U.S.C. § 706(2)(D).

130. AIS has suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(D).

131. AIS is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT V
(Violation Of Due Process – U.S. CONST. AMEND. V)

132. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

133. The DEA's December 14, 2023 directive – as approved and directed by Defendants – is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

134. AIS is adversely affected and aggrieved by the directive.

135. The Fifth Amendment forbids the deprivation of "life, liberty, or property without due process of law."

136. AIS possesses a property interest in its DEA registration.

137. Defendants issued the directive to AIS without providing an order to show cause or a statement of findings regarding the danger to public health or safety posed by shipments of AIS's compounded medications "directly to the practitioner."

138. Accordingly, Defendants violated AIS's due process rights by failing to afford it adequate procedural rights before issuing the directive, thereby constructively revoking and/ or suspending AIS's DEA registration.

139. AIS has suffered and will continue to suffer irreparable harm as a result of Defendants' violation of its constitutional rights.

140. AIS is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief.

COUNT VI
(Declaratory Judgment)

141. AIS re-alleges and incorporates Paragraphs 1 through 92 as if fully set forth herein.

142. The DEA's December 14, 2023 directive is a final agency action made reviewable by 5 U.S.C. § 706(2) and 21 U.S.C. § 824(d).

143. AIS is adversely affected and aggrieved by the directive.

144. An actual controversy has arisen and exists between AIS and Defendants regarding Defendants' directive that AIS to "cease and desist any further shipments directly to the practitioner."

145. AIS requests a declaration from this Court under 28 U.S.C. § 2201 that Defendants' directive is unlawful, violates federal law, and violates AIS's constitutional rights.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AIS prays that this Court:

1. Declare that:

- Defendants' directive and issuance of the same is arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A);
- Defendants have violated AIS's due process rights in violation of 5 U.S.C. § 706(2)(B) by issuing their cease and desist directive;
- Defendants have acted in excess of statutory authority in violation of 5 U.S.C. § 706(2)(C) by issuing their cease and desist directive;
- Defendants have unlawfully acted without observing and complying with mandatory procedures in violation of 5 U.S.C. § 706(2)(D) by issuing their cease and desist directive; and
- Defendants have violated AIS's constitutional rights in violation of U.S. Const. Amend. V by issuing their cease and desist directive.

2. An injunction:

- Preliminarily and permanently enjoining Defendants from revoking, limiting, or others interfering with AIS's DEA registration;
- Preliminarily and permanently enjoining Defendants from directing and/ or ordering AIS to cease and desist from, or otherwise interfering in any way with, AIS's dispensing of medications to treating physicians; and
- Directing Defendants to withdraw the cease and desist directive.

3. Award AIS its reasonable attorney's fees and costs as appropriate.

4. Grant such other further relief as this Court deems just and proper.

Dated: December 15, 2023

Respectfully submitted,

/s/ Michael Casey Williams

J. William Manuel (MSB 9891)
Michael Casey Williams (MSB 104537)
Christina M. Seanor (MSB 104934)
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DECLARATION

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the factual statements contained in the Verified Complaint related to Plaintiff Bond Pharmacy, d/b/a AIS Healthcare, are true and correct to the best of my knowledge and belief.

Ross Kamm
Chief Financial Officer
Bond Pharmacy, d/b/a AIS Healthcare

Executed on: December 15, 2023